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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/221,931	12/28/1998	TAKASHI TSURUO	WAKAB37.001A	3902

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No. 09/221,931	Applicant(s) TSURUO ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-32, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 26-32, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Status of Claims

1. Claim 1-25,33 are canceled. Claim 35 is added. Claims 26-32,34,35 are pending. Claims 26-32,34 are amended.

2. Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, second paragraph.

3. Claim 26 (and claims 27-32,34 dependent thereupon) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 26 is amended to read on topical administration or administration by injection. It is not clear what species (humans, mammals, birds, etc.) are subject of the treatment.

B. Claim 26 lacks internal antecedent basis as it recites "the solution" at the end of the claim; however, no solution is addressed in the preceding portion of the claim.

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C. Claim 31 is confusing. The base claim 26 addresses use of epigallocatechin in solution, while claim 31 is directed to use of powdered tea extract.

D. Claim 28 is unclear. Does the concentration of claim 26 address only one component of the composition, or cumulative concentration?

E. Claims 30, 31: composition can not comprise 10% (as in claim 31), and even less so 90-95% (as in claim 30, wherein composition comprises one catechin) of catechin, as the concentration is defined by the new limitation of claim 26 as being 5-15 μM , which is much less than the above concentration (e.g., 10% EGCG is equivalent to 344 μM)

Claim Rejections - 35 USC § 112, first paragraph.

4. Claims 26-32,34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 26 introduces new matter as it is amended to read on topical administration or administration by injection of solution of epigallocatechin gallate (EGCG), wherein said solution has EGCG in concentration 5-15 μM . There is no disclosure in the specification of any *in vivo* administration of catechin composition containing solution

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with 5-15 μ M EGCG. Contrary, the only indication of *in vivo* dosage, on p. 5, last paragraph, indicates the range of about two orders higher.

5. Claims 27,28,30,31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 26 introduces new matter as it is amended to read on administration of a mixture of catechins containing one particular catechin, EGCG in concentration 5-15 μ M. There is no disclosure of administration of such mixtures.

6. Claim 26-32,34 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The claims are drawn to administering catechin composition comprising 5-15 μ M EGCG. However, specification clearly teaches that in the case of *in vivo* administration, the amount of EGCG should be substantially higher (100-500mg/dose), it does not provide guidance on how to achieve, *in vivo*, the expected effect at concentration of 5-15 μ M, which is substantially lower than indicated in the specification.

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Claim Rejections - 35 U.S.C. § 102

7. Claim 35 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over JP 910108977.

JP 910108977 teaches that catechins obtained from green tea concentrates prevented development of colon cancer. It is known in the prior art that 1) green tea is effective as a cancer preventive, 2) catechins are known to be active ingredients of green tea or green tea extracts; 3) telomerase is active in cancer cells and is dormant in normal cells. The catechins were purified from green tea to 93% purity. The preferred concentration of catechins is 0.05-0.7% (see abstract), which is equivalent to range 1.7-24 μ M (calculated using 290.3 as the molecular weight of catechin; as provided for product #9510 in Sigma catalog).

Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. In the instant case, the only method step as instantly claimed is contacting cells (ie via administration) with a composition comprising a catechin. It is Examiner's position that any reference teaching exposure of cells, *in vitro* or *in vivo*, to a composition comprising catechins

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(e.g., green tea) in its normal and usual operation would necessarily perform the method as claimed because prevention of cancer prevents telomerase activity.

Conclusion.

8. No claims are allowed

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-

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0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

February 20, 2004

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', with a long, sweeping horizontal stroke extending to the right.